

**ATTACHMENT A**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	Volkert A. Zeijlemaker et al.	Examiner:	J.F. Ramirez
Serial No.	10/673,777	Group Art Unit:	3737
Filing Date:	September 29, 2003	Docket No.:	P0010499.00
Title:	TIMING TECHNIQUES FOR MAGNETIC RESONANCE IMAGING		

---

**RESPONSE TO FINAL OFFICE ACTION**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is in response to the Final Office Action dated June 9, 2008.

The claims begin on page 2 of this Amendment. Please amend the claims as set forth below.

Remarks begin on page 6 of this Amendment.

**IN THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

1. (Currently amended) A method of performing magnetic resonance imaging (MRI) on ~~a volume of~~ tissue of a patient having an implantable medical device (IMD) with a telemetry unit communicating timing information as to operational conditions of the IMD, comprising:

receiving the timing information communicated from ~~[[an]] the implantable medical device (IMD);~~

applying a plurality of discrete MRI electromagnetic radiation bursts to the ~~volume of~~ tissue of the patient, wherein said applied radiation bursts are synchronized with operational conditions of the IMD based upon the received timing information;

imaging the ~~volume of~~ tissue upon a display, whereby the imaged tissue is displayed in a substantially common state during each of said plurality of radiation bursts.

2. (Currently amended) A method according to claim 1, further comprising sensing cardiac activity with the IMD and wherein the timing information includes timing of sensed cardiac activity ~~conditions measured by the IMD on a beat-by-beat basis, and wherein the volume of tissue comprises myocardial tissue.~~

3. (Currently amended) A method according to claim ~~[[2]]~~ 1, further comprising sensing physiologic conditions of the patient with the IMD.

4. (Currently amended) A method according to claim 1, further comprising applying cardiac pacing pulses using the IMD and wherein the timing information

defines [[a]] timing of cardiac pacing stimulation pulses applied to the patient by the IMD.

5. (Currently amended) A method according to claim [[2]] 1, further comprising:

stimulating a patient with the IMD based upon ~~a plurality of different~~ the timing information to produce, ~~wherein the plurality of different timing information produces a plurality of different~~ a specified cardiac activity rhythm;

imaging the ~~myocardial~~ heart tissue based on the ~~timing of the plurality of~~ different timing information during application of the stimulation applied to the patient by the IMD; and

at least one of storing and displaying at least some of said plurality of images when the ~~myocardial~~ heart tissue is at common points during the produced cardiac rhythm.

6. (Currently amended) The method of claim 5, wherein ~~at least one of said plurality of different~~ stimulation based on the timing information is intended to induce an arrhythmia.

7. (Previously presented) The method of claim 1, wherein the IMD is a pacemaker and wherein the timing information defines a timing of a cardiac cycle.

8. (Previously presented) The method of claim 1, wherein performing the MRI includes applying one or more electromagnetic radiation bursts based on the timing information.

9. (Previously presented) The method of claim 1, wherein performing the MRI includes applying one or more gradient magnetic fields based on the timing information.

10. (Currently amended) A method of performing magnetic resonance imaging (MRI) on a patient ~~having~~ stimulated by an implantable medical device (IMD) ~~with~~ having a telemetry unit communicating stimulation timing information ~~as to operational conditions of the IMD~~, comprising:

stimulating a patient with ~~an implantable medical device~~ the (IMD) ~~with a plurality of different~~ based upon the stimulation timing information ~~sets~~;

transmitting the ~~operating~~ stimulation timing information ~~indicative of the plurality of different timing information sets of the stimulation from the IMD~~;

receiving at an MRI device the ~~operating~~ stimulation timing information transmitted from the IMD; and

responsive to receipt of the timing information by the MRI device, applying a plurality of electromagnetic radiation bursts from the MRI device to the patient synchronized with the timing information ~~sets~~, whereby tissue being imaged is placed in a substantially common state during each ~~common one~~ of said plurality of electromagnetic bursts.

11. (Currently amended) The method of claim 10, further comprising:

sensing conditions of the patient with the IMD;

communicating ~~sensed conditions~~ sensing timing information indicative of the sensed conditions to the MRI device; and

applying the MRI radiation bursts to the patient synchronized with the ~~timing of one of the stimulation timing information and the sensed conditions~~ sensing timing information.

12.-18. (Canceled)

19. (Cancelled)

20. (Cancelled)

21.-25. (Cancelled)

26. (Currently amended) An apparatus comprising:
- means for receiving ~~a plurality of different~~ timing information from an cardiac-based implantable medical device (IMD) related to timed operating conditions of the IMD;
  - means for performing magnetic resonance imaging (MRI) of ~~a volume of myocardial~~ heart tissue by applying electromagnetic radiation ~~bursts~~ based upon the ~~plurality of different~~ received timing information; and
  - means for synchronizing application of electromagnetic radiation ~~bursts~~ with the ~~plurality of different~~ received timing information, whereby the ~~volume of myocardial~~ heart tissue being imaged is placed in a substantially common state during each application of radiation ~~burst that is based upon a common one~~ timing information of said ~~plurality of different timing information~~.
27. (New) An apparatus according to claim 26, wherein the IMD comprises means for sensing cardiac activity wherein the timing information includes timing of sensed cardiac activity.
28. (New) An apparatus according to claim 26, wherein the IMD comprises means for applying cardiac stimulation pulses and wherein the timing information defines timing of cardiac stimulation pulses applied to the patient by the IMD to produce a specified cardiac rhythm.
29. (New) An apparatus according to claim 28, wherein the MRI comprises:
- means for imaging the cardiac tissue during application of the cardiac stimulation by the IMD based upon the timing information; and
  - means for storing and displaying a plurality of images taken during common points during the produced cardiac rhythm.
30. (New) The apparatus of claim 29, wherein cardiac stimulation based on the timing information is adapted to induce an arrhythmia.

31. (New) The apparatus of claim 26, wherein the IMD comprises a pacemaker and wherein the timing information defines a timing of a cardiac cycle.

32. (New) The apparatus of claim 26, wherein the MRI comprises means for applying one or more electromagnetic radiation bursts based on the timing information.

33. (New) The apparatus of claim 26, wherein the MRI comprises means for applying one or more gradient magnetic fields based on the timing information.

34. (New) An apparatus for performing magnetic resonance imaging using an MRI device (MRI) on a patient having an implantable medical device (IMD), wherein the IMD comprises:

means for stimulating the patient based upon timing information; and

means for transmitting the timing information from the IMD; and wherein

the MRI comprises:

means for receiving the timing information transmitted from the IMD; and

means responsive to receipt of the timing information, for applying

electromagnetic radiation to the patient synchronized with the timing information, whereby tissue being imaged is placed in a substantially common state during each of the applications of electromagnetic radiation.

35. (New) The apparatus of claim 34, further comprising:

means for sensing conditions of the patient with the IMD;

means for communicating sensing timing information indicative of the sensed conditions to the MRI device; and wherein the MRI comprises:

means for applying the electromagnetic radiation synchronized with the timing information.

App. No. 10/673,777  
Art Unit: 3737  
Page 7 of 10

### **Remarks**

Claims 1 – 11, 19 – 20 and 26 are pending. By means of the present amendment, claims 19 and 20 are cancelled. Claims 1 – 6, 10, 11 and 26 are currently amended. Claims 7 – 9 remain as previously presented. New claims 27 – 35 are added.

The discussion of the rejections set forth below applies equally to claims 1 – 11 and 26 as filed and to these claims as amended. The filed and amended claims are all believed to be patentable over the cited references for the reasons discussed below.

In the Final Office Action, claims 1 – 11 and 26 were rejected as obvious over the combination of Foster, et al. and Paul et al. This rejection is respectfully traversed. In the Final Office Action, it is stated that the Foster, et al patent teaches “a receiver to received information from an implantable medical device(IMD) (abstract)...” This observation is respectfully traversed. The Abstract of Foster, et al refers only to the cardiac assist device, i.e., the IMD. No mention is made of a receiver for signals from the IMD. While it is understood generally that programmers exist to receive information from IMD's, there is no hint in the Abstract as cited that the transmitted information should somehow influence the delivery of MRI scans.

The Office Action further states that the Foster, et al reference teaches “a control unit to coordinate the application of the electromagnetic radiation bursts based on the information (see Figure 5)”. This observation is also respectfully traversed. Figure 5 shows the response of the IMD to optical signals received from the MRI unit by the IMD . There is no disclosure of the MRI unit coordinating its activities based on signals transmitted from the IMD.



The Office Action then states that the Foster, et al. reference teaches “the information defines a timing of stimulation pulses applied to the patient by the IMD (col.7, lines 5 – 67). This observation is also respectfully traversed. The cited language describes communication within the IMD between the portion that stays operational during the MRI procedure and the portion that shuts down. The information transmitted between the modules only relates to turning on the modules on and off. There is no disclosure that even the fact of the activation or deactivation of the modules is ever telemetered to an external device. Further, during the MRI procedure, in this embodiment of the Foster, et al device, the portion of the device that is capable of telemetering information to an external device is disabled. The portion of the circuitry of this embodiment of the Foster, et al. invention that stays active during the MRI procedure runs completely asynchronous to the MRI device, simply generating pacing pulses asynchronously until an internal half hour timer expires. Similarly, the portion of the circuitry of the pacemaker that senses cardiac events is disabled during the MRI. There is no teaching in the Foster, et al reference that any information as to the timing of the IMD during MRI procedures is transmitted from the IMD under any circumstances. There is no possible way to synchronize delivery of MRI radiation to sensed or paced events during MRI procedures.

The observations discussed above are fundamental to the rejection of claims 1 – 11 and 26. Because the rejection of the claims depends upon these observations, it is respectfully asserted that the rejection of claims 1 – 11 and 26 is unsupported and that it should be withdrawn.

Claims 2, 3, 7 and 11 were all also rejected over Foster, et al. This rejection is expressly based on the premise that Foster, et al. teaches all of claim 1 except for the limitations of claims, 2, 7 and 11. However, as discussed previously, this is not believed to be the case. As such, it is respectfully asserted that the rejection of claims 2, 3, 7 and 11 is unsupported and that this rejection should also be withdrawn.

Claims 1 – 6 and 26 have been amended to correct the deficiencies noted under section 112 and are now believed unobjectionable. No new substantive limitations were added to the amended claims other than the substitution of “heart” for “myocardial” (supported in PP 022) and the clarification that the MRI radiation is applied at common time points during the cardiac rhythm (supported in PP 006 and PP 022). No new matter is added to the claims as a result of the amendments.

New claims 27 – 35 have been added and are apparatus claims paralleling the method claims 2 – 11 as discussed above. These added claims are believed supported by the specification and patentable over the cited references for the same reasons as the method claims discussed above.

### **Conclusion**

Entry of the present amendment, reconsideration of the rejections of claims 1 – 11 and 26, as filed and as amended, along with consideration of newly submitted claims 26 – 35 is respectfully requested. The Examiner is invited to contact the undersigned with any questions regarding this application.

Respectfully submitted,

Date: September 8, 2008

/Reed A. Duthler/  
Reed A. Duthler  
Reg. No. 30,626  
Telephone: (763) 526-1564  
Customer No. 27581